



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,443	08/14/2001	Jack Price	GJE-74	9647

7590 02/25/2004

GLENN P. LADWIG
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 32606-6669

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2/1/03

Office Action Summary

Application No.

09/913,443

Applicant(s)

PRICE, JACK

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-7 and 10-14 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 12/12/03
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____

DETAILED ACTION

Claims 1-6, 10-13 are pending.

This Office Action is in response to the Amendment filed on 12/8/03.

Response to Amendment

The objection to the specification has been withdrawn in light of Applicant's clarification.

The rejection of claims 1-7 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-7 and 10-14 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 7/3/03 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicant argues that the specification teaches how to harvest cells from mice as indicated in the Chopp abstract, and this abstract further teaches that the hematopoietic stem cells express neuronal or astrocytic phenotype post intracerebral

Art Unit: 1636

transplantation. Applicant further argues that there is no rationale for presuming human cells would not differentiate into neural cells as mouse cells as disclosed by Chopp et al. base on the NIH publication. Applicant also presents Weimann et al. to demonstrate that human bone marrow cells do indeed have the capability of forming effective neural cells in human adult brains. Moreover, Applicant argues that there is no rationale for concluding that the *in vivo* results obtained using mouse model would not reasonably correlate with human patients, and a cure of the disease condition or clinical efficacy is not required to satisfy the enablement requirement (Scott v. Finney). Applicant further argues that the Mezey reference does not prove the difficulties for using bone marrow cells for therapy. Lastly, Applicant argues that the route of administration of the hematopoietic stem cells does not represent an obstacle to the practice of the subject invention because conventional neural cell transplantation technique can be used. Therefore, Applicant concludes the invention is enabled by the instant specification.

These arguments have been fully considered but deemed unpersuasive. The reasons for the enablement rejection was discussed in detail in the office action mailed on 7/3/03. Applicant is reminded that the rejection is based on an overall analysis of the Wands factors, including the nature of the invention, the breadth of the claims, the state of the prior art and the level of predictability in the art, the amount of direction provided by the inventor and the existence of working examples, and whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue", rather than a single technical difficulty based on the prior art. The state of art at the time of filing indicate that the stem cell therapy is unpredictable due to factors discussed previously (see pages 4-5 of the previous office action, especially about Parkinson's disease). Although Chopp et al. teaches that the

Art Unit: 1636

transplanted hematopoietic stem cells expresses neuronal or astrocytic phenotype, this reference does not teach whether these cells would develop into fully functional neurons and/or such transplantation would achieve therapeutic effect on any type of sensory, motor/cognitive deficit. The breadth of the claim encompasses a method of treating any type of sensory, motor/cognitive deficit by administering a hematopoietic stem cell intracerebrally. Although Applicant does not have to show complete cure of the disease or clinical efficacy of said method, Applicant has to demonstrate that the sensory, motor/cognitive deficit can be treated by the claimed method without undue experimentation. However, the specification does not teach any therapeutic effect can be achieved by the claimed method.

As discussed in the previous office action, the NIH publication and Mezey et al. indicate that not all information from mouse stem cells can be translated to human cells. The Weimann reference cannot be relied on to support the enablement of the claimed invention because the claimed invention has to be enabled at the time the invention was made. In the instant case, Weimann et al. was published in the year 2003, 4 years after the priority date of the current application. Moreover, this reference fails to teach that the transplantation of a human hematopoietic stem cell would achieve any therapeutic effect in treating any type of sensory, motor/cognitive deficit. Based on the teaching of prior art and the specification, although the hematopoietic cell can be transplanted intracerebrally as indicated by Applicant, whether it can treat any sensory, motor/cognitive deficit is unpredictable. Therefore, for reasons set forth in the previous office action and above, one skilled in the art would have to engage in undue experimentation to practice the method as claimed. As such, the claimed method is not enabled.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

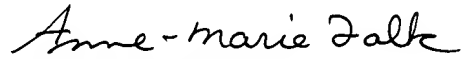
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER